SAH

PATENT

6.19.01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Atty. Docket No. 98-541-C)

In re Application of:)
)
Christensen *et al.*)
)
Serial No.: 09/721,096)
)
Filed: November 22, 2000)
)
For: Removal of Embedding Media from Tissue Samples and Cell Tissue Conditioning in Automated Immuno-histochemical Instrumentation)

Bex

Examiner: ~~Not Assigned~~

Group Art Unit: 1743

Confirmation No. 4217

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.97 & 1.98, the Applicants wish to make the following references listed on the enclosed Form PTO/SB/08 of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56.

Copies of the references cited on the Form PTO/SB/08 are enclosed. Also, attached to each reference in a language other than English is a translation of that reference or an explanation of the relevance of that reference in accordance with 37 C.F.R. § 1.98 (a) (3). For Information Disclosure Statements submitted after receipt of a foreign Search Report, a copy of such Search Report is attached.

The Examiner is respectfully requested to consider the references in their entirety and to so indicate by initialing the appropriate box on the Form PTO/SB/08. The filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made. Likewise, the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

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300 South Wacker Drive
Chicago, IL 60606
(312) 913-0001

Exp. Mail No.: EL 738004947 US

U.S. Patent Documents

5,244,787	Key *et al.*	September 14, 1993
5,273,905	Muller *et al.*	December 28, 1993
4,043,292	Rogers *et al.*	August 23, 1977
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Other Documents

1. **Bankfalvi, A. *et al.*** (1994) "Wet autoclaving pretreatment for antigen retrieval in diagnostic immunohistochemistry." *Journal of Pathology* **174**: 223-228.
2. **Fox, C.H. *et al.*** (1985) "Formaldehyde fixation." *Journal of Histochemistry and Cytochemistry* **33 (8)**: 845-853.
3. **Kawai, K. *et al.*** (1994) "Heat-induced antigen retrieval of proliferating cell nuclear antigen and p53 protein in formalin-fixed, paraffin-embedded sections." *Pathology International* **44**: 759-764.
4. **Mason, J.T. & O'Leary, T.J.** (1991) "Effects of formaldehyde fixation on protein secondary structure: a calorimetric and infrared spectroscopy investigation." *Journal of Histochemistry and Cytochemistry* **39 (2)**: 225-229.

5. **MaWhinny, W.H.B. *et al.*** (1990) "Automated immunohistochemistry." *Journal of Clinical Pathology* **43**: 591-596.

6. **McNicol, A.M. & Richmond, J.A.** (1998) "Optimizing immunohistochemistry: antigen retrieval and signal amplification." *Histopathology* **32**: 97-103.

7. **Miller, R.T. & Estran, C.** (1995) "Heat-induced epitope retrieval with a pressure cooker." *Applied Immunohistochemistry* **3 (3)**: 190-193.

8. **Morgan, J.M. *et al.*** (1994) "Possible role of tissue-bound calcium ions in citrate-mediated high-temperature antigen retrieval." *Journal of Pathology* **174**: 301-307.

9. **Norton, A.J. *et al.*** (1994) "Brief, high-temperature heat denaturation (pressure cooking): a simple and effective method of antigen retrieval for routinely processed tissues." *Journal of Pathology* **173**: 371-379.

10. **Pasha, T. *et al.*** (1995) "Nuclear antigen retrieval utilizing steam heat." *Laboratory Investigations* **72**: 167A, abstract #979.

11. **Pertschuk, L.P. *et al.*** (1994) "Estrogen receptor immunocytochemistry: the promise and the perils." *Journal of Cellular Biochemistry* **suppl. 19**: 134-137.

12. **Pons, C. *et al.*** (1995) "Antigen retrieval by wet autoclaving for p53 immunostaining." *Applied Immunohistochemistry* **3 (4)**: 265-267.

13. **Shi, S.-R. *et al.*** (1997) "Antigen retrieval immunohistochemistry: past, present, and future." *Journal of Histochemistry and Cytochemistry* **45 (3)**: 327-343.

14. **Sibony, M. *et al.*** (1995) "Methods in laboratory investigation: Enhancement of mRNA *in situ* hybridization signal by microwave heating." *Laboratory Investigation* **73 (4)**: 586-591.

15. **Sperry, A. *et al.*** (1996) "Microwave treatment enhances detection of RNA and DNA by in situ hybridization." *Diagnostic Molecular Pathology* **5 (4)**: 291-296.

16. **Stark, E. *et al.*** (1988) "An automated device for immunohistochemistry." *Journal of Immunological Methods* **107**: 89-92.

17. **Stross, W.P. *et al.*** (1989) "Automation of APAAP immunocytochemical technique." *Journal of Clinical Pathology* **42**: 106-112.

18. **Taylor, C.R. *et al.*** (1995) "A comparative study of antigen retrieval heating methods." *CAP Today* **9**: 16-22.

19. International Search Report for application PCT/US99/20353.

20. International Search Report for application PCT/US99/04379.

21. International Search Report for application PCT/US99/04181.

This Information Disclosure Statement is being filed:

☒ within three months of the filing date of a national application; within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 in an international

application; or before the mailing date of a first Office Action on the merits. 37 C.F.R. §1.97 (b)

☐ **after** three months of the filing date of a national application, or the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 in an international application; or **after** the mailing date of a first Office Action on the merits, but **before** the mailing date of a Final Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311 (whichever occurs first), and includes (37 C.F.R. § 1.97 (c):

☐ the Certification under 37 C.F.R. § 1.97(e) (see "Certification" below)

OR

☐ the fee of $180 set forth in 37 C.F.R. § 1.17(p) (see "Fees" below).

☐ **after** a Final Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311 (whichever occurs first), but before, or simultaneously with, the payment of the issue fee, and includes the Certification under 37 C.F.R. § 1.97(e) (see "Certification" below), and the Petition Fee set forth in 37 C.F.R. § 1.17(i) (see "Fees" and "Method of Payment of Fees" below). Applicants hereby petitions for consideration of the Information Disclosure Statement submitted herewith and the accompanying references in examination of the subject patent application.

CERTIFICATION

☐ The **undersigned** hereby certifies that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

☐ The **undersigned** hereby certifies that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

FEES

☒ **No fee** is owed by the applicant(s).

☐ The **IDS Fee of $180.00** under 37 C.F.R. § 1.17(p) is enclosed herewith.

☐ The **Petition Fee of $130.00** set forth in 37 C.F.R. § 1.17(i) is enclosed herewith.

METHOD OF PAYMENT OF FEES

☐ Attached is a check in the amount of $.

☐ Charge Deposit Account No. 13-2490 in the amount of $. (A duplicate copy of this communication is enclosed for that purpose.)

FILING OF CORRESPONDENCE BY EXPRESS MAIL UNDER 37 CFR § 1.10

The undersigned states that this Information Disclosure Statement and any documents referred to herein as being attached or enclosed are being deposited as Express Mail to Addressee (Express Mail No.: EL 738004947 US) with the United States Postal Service with sufficient postage in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231 on May 18, 2001.

REMARKS

Consideration of the cited information herein is respectfully requested. Should there be any questions regarding this Information Disclosure Statement, the Examiner is invited to contact the undersigned. Please charge any underpayment or credit any overpayment of fees occasioned by this communication to Deposit Account No. 13-2490.

Respectfully submitted,

Date: May 18, 2001

Mark L. Chael, Ph.D.
Registration No. 44,601

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	3	of	4

Complete if Known	
Application N .	09/721,096
Filing Date:	November 22, 2000
First Named Inventor	Christensen
Group Art Unit	1743
Examiner Name	unassigned
Attorney Docket No.	98,541-C

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
	T	**Bankfalvi, A. *et al.*** (1994) "Wet autoclaving pretreatment for antigen retrieval in diagnostic immunohistochemistry." *Journal of Pathology* **174**: 223-228.	
	U	**Fox, C.H. *et al.*** (1985) "Formaldehyde fixation." *Journal of Histochemistry and Cytochemistry* **33 (8)**: 845-853.	
	V	**Kawai, K. *et al.*** (1994) "Heat-induced antigen retrieval of proliferating cell nuclear antigen and p53 protein in formalin-fixed, paraffin-embedded sections." *Pathology International* **44**: 759-764.	
	W	**Mason, J.T. & O'Leary, T.J.** (1991) "Effects of formaldehyde fixation on protein secondary structure: a calorimetric and infrared spectroscopy investigation." *Journal of Histochemistry and Cytochemistry* **39 (2)**: 225-229.	
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	Y	**McNicol, A.M. & Richmond, J.A.** (1998) "Optimizing immunohistochemistry: antigen retrieval and signal amplification." *Histopathology* **32**: 97-103.	
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	AB	**Norton, A.J. *et al.*** (1994) "Brief, high-temperature heat denaturation (pressure cooking): a simple and effective method of antigen retrieval for routinely processed tissues." *Journal of Pathology* **173**: 371-379.	
	AC	**Pasha, T. *et al.*** (1995) "Nuclear antigen retrieval utilizing steam heat." *Laboratory Investigations* **72**: 167A, abstract #979.	
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	AF	**Shi, S.-R. *et al.*** (1997) "Antigen retrieval immunohistochemistry: past, present, and future." *Journal of Histochemistry and Cytochemistry* **45 (3)**: 327-343.	
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	AH	**Sperry, A. *et al.*** (1996) "Microwave treatment enhances detection of RNA and DNA by in situ hybridization." *Diagnostic Molecular Pathology* **5 (4)**: 291-296.	

Examiner Signature	Kathryn Bex	Date Considered	10/11/02

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 4

Complete if Known	
Application N .	09/721,096
Filing Date:	November 22, 2000
First Named Inventor	Christensen
Group Art Unit	MAY 22 2001 1743
Examiner Name	unassigned
Attorney Docket No.	98,541-C 1700

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
	AI	**Stark, E. *et al.*** (1988) "An automated device for immunohistochemistry." *Journal of Immunological Methods* **107**: 89-92.	
	AJ	**Stross, W.P. *et al.*** (1989) "Automation of APAAP immunocytochemical technique." *Journal of Clinical Pathology* **42**: 106-112.	
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	AL	International Search Report for application PCT/US99/20353.	
	AM	International Search Report for application PCT/US99/04379.	
	AN	International Search Report for application PCT/US99/04181.	

Examiner Signature		Date Considered	10/1/02

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Sheet 1 of 4

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Filing Date:	November 22, 2000
First Named Inventor	Christensen
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Examiner Name	unassigned
Attorney Docket No.	98,541-C

MAY 22 2001
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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	U.S. Patent Document Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Figures Appear
	A	5,244,787		Key *et al.*	09-14-1993	
	B	5,273,905		Muller *et al.*	12-28-1993	
	C	4,043,292		Rogers *et al.*	08-23-1977	
	D	5,023,187		Koebler *et al.*	06-11-1991	
	E	5,614,376		Copley *et al.*	03-25-1997	
	F	5,595,707		Copeland *et al.*	01-21-1997	
	G	5,601,141		Gordon *et al.*	02-11-1997	
	H	4,858,155		Okawa *et al.*	08-15-1989	
	I	4,865,986		Coy *et al.*	09-12-1989	

FOREIGN PATENT DOCUMENTS

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	J	WO	93/09486		Hybaid Ltd.	05-13-1993		

Examiner Signature		Date Considered	10/11/02

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sheet 2 of 4

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